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10/601,007	06/20/2003	Satoshi Masaoka	AK-419XX	5771

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BOSTON, MA 02109

EXAMINER

CONLEY, SEAN EVERETT

ART UNIT	PAPER NUMBER
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1744

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/601,007

Applicant(s)

MASAOKA ET AL.

Examiner

Sean E. Conley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 14-25,30,31,34 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13,26-29,32 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/2/2006.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I, claims 1-13, 26-29, and 32-33 in the reply filed on November 2, 2006 is acknowledged. The traversal is on the ground(s) that examination of all of the claims does not impose an undue burden on the examiner. This is not found persuasive because the inventions of groups I and II are classified in different classes and therefore they each require a separate search. Thus conducting a search for both of the inventions would be a burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-13, 26-29, and 32-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "normal" in claims 1 and 7 is a relative term which renders the claim indefinite. The term "normal" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 2-6, 8-13, 26-29, and 32-33 are rejected because they depend from and include all of the limitations of either claim 1 or 7.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 3, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Menashi (U.S. Patent No. 3,383,163) in view of Nam et al. (U.S Patent Application Publication 2002/0063537 A1).

Regarding claim 1, Menashi discloses a method of sterilizing surfaces of containers (packaging material) by exposing the surfaces to a plasma for a time

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sufficient to destroy the microorganisms (see col. 1, lines 10-20; figure 3). The device comprises a high voltage pulse power source (power supply (19)), a discharge side electrode (18) attached to the power supply (19), a ground side electrode (22) arranged so as to be opposed to the discharge side of the discharge side electrode (18), and an argon gas inlet conduit (31). The surfaces of the container are placed between the electrodes and the surfaces are sterilized by applying high voltage pulses to the discharge electrode (18) which generates plasma in the argon gas atmosphere under atmospheric conditions (see figure 3; see col. 2, lines 38-72; see col. 3, lines 58-68; see col. 4, lines 45-73). Menashi fails to teach a discharge side electrode provided with unevenness having continuous projections on the discharge side surface of the electrode.

Nam et al. discloses an apparatus for generating a low temperature plasma at atmospheric pressure that includes a discharge electrode (conductor electrode (5)) provided with unevenness having continuous projections (tips (8, 8', 8'')) along the length of the electrode (5) as shown in figures 3A-3C. These continuous projections facilitate the discharging of the charges which are accumulated in the electrode (see paragraph [0029]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Menashi and include continuous projections on the discharge electrode (18) in order to facilitate and the release of the charges accumulated with the electrode as taught by Nam et al.

Regarding claim 3, Menashi discloses a process for sterilizing containers by generating a plasma (see col. 1, lines 10-20, col. 1, line 69-col. 2, line 8).

Regarding claim 5, Menashi discloses that the gas is selected from the group comprising argon, helium, nitrogen, xenon, and the like (see col. 4, lines 45-52).

Regarding claim 6, Menashi discloses that the plasma forming gas (e.g. argon) flows down through neck (32) of the gas inlet conduit (31) and sweeps the plasma formed at the corona discharge up through the bottle and out of the opening (see col. 3, lines 25-29, 58-68). Thus, the gas is introduced during discharge.

6. Claims 7-9, 12, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Menashi in view of Perruchot et al. (Patent Application Publication 2004/0037736 A1).

Regarding claims 7-9, and 29 Menashi discloses a method of sterilizing surfaces of containers (packaging material) by exposing the surfaces to a plasma for a time sufficient to destroy the microorganisms (see col. 1, lines 10-20; figure 3). The device comprises a high voltage pulse power source (power supply (19)), a discharge side electrode (18) attached to the power supply (19), a ground side electrode (22) arranged so as to be opposed to the discharge side of the discharge side electrode (18), and an argon gas inlet conduit (31). The surfaces of the container are placed between the electrodes and the surfaces are sterilized by applying high voltage pulses to the discharge electrode (18) which generates plasma in the argon gas atmosphere under atmospheric conditions (see figure 3; see col. 2, lines 38-72; see col. 3, lines 58-68; see

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col. 4, lines 45-73). Menashi fails to teach the step of giving water or an aqueous solution to the packaging material before discharge, during discharge or before and during discharge.

Perruchot et al. discloses a plasma sterilization system that sterilizes surfaces of articles using plasma generated from a corona discharge produced by electrodes in the presence of oxygen, nitrogen, or hydrogen gas (see paragraphs [0016]-[0017], [0024], [0046]. The process improves on conventional plasma sterilization systems by humidifying the oxygen, nitrogen, or hydrogen gas prior to introducing the gas in the discharge zone of the electrodes (see paragraph [0046]). The process gas flows from a source (12) through a humidification chamber (14) where the gas is supplied with water vapor (see paragraphs [0054], [0059] and [0084]). The discharge of the plasma and the humidification of the gas are simultaneous (see paragraph [0024]). The resulting humidification of the gas provides a higher humidity in the vicinity of the article which results in shorter sterilization times and also decreases the temperature of the surfaces of the article being treated which prevents a decrease in the sterilization effects caused by heating of the article due to plasma exposure (see paragraph [0078], see table 2). Although it is not specifically recited, the water vapor present in the plasma forming gas (e.g. oxygen, nitrogen, or hydrogen) will cloud the surface of the article being treated when the humidified gas is introduced to the article.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Menashi and provide the surface of the container with water in the form of water vapor entrained in the plasma forming

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gas (e.g. hydrogen, nitrogen, oxygen) which is introduced during discharge as taught by Perruchot et al. in order to decrease the sterilization time of the process and also decrease the temperature of the surfaces being treated which prevents any decrease in the effectiveness of the sterilization resulting from heat generated on the container by the plasma.

Regarding claim 12, Menashi discloses a process for sterilizing containers by generating a plasma (see col. 1, lines 10-20, col. 1, line 69-col. 2, line 8).

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Menashi in view of Perruchot et al. as applied to claim 7 above, and further in view of Nam et al.

The combination of Menashi and Perruchot et al. fail specifically to teach a discharge side electrode provided with unevenness having continuous projections on the discharge side surface of the electrode.

Nam et al. discloses an apparatus for generating a low temperature plasma at atmospheric pressure that includes a discharge electrode (conductor electrode (5)) provided with unevenness having continuous projections (tips (8, 8', 8'')) along the length of the electrode (5) as shown in figures 3A-3C. These continuous projections facilitate the discharging of the charges which are accumulated in the electrode (see paragraph [0029]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Menashi and include continuous

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projections on the discharge electrode (18) in order to facilitate and the release of the charges accumulated with the electrode as taught by Nam et al.

8. Claims 2 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Menashi in view of Nam et al. as applied to claim 1 above, and further in view of Dusevoir (U.S. Patent No. 3,819,985).

Regarding claim 2, Menashi and Nam et al. disclose the claimed invention except for a discharge electrode with a surface that is helical.

Dusevoir discloses a discharge electrode (34') for generating a corona discharge that includes an outer sheath (48') having integral ribs (54') helically formed. The helical ribs increase the corona discharge of the electrode (34') by increasing the effective area of the ribs (see col. 2, lines 58-66; see figure 4). Furthermore, the use of long thin solid wire electrodes tend to break easily due to concentration of electrical discharge at certain points thereon and due to material fatigue (see col. 1, lines 25-38).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Menashi and provide a discharge electrode having helical ribs as taught by Dusevoir in order to increase the corona discharge of the electrode and also provide an electrode that will not easily break by using the helical ribs to evenly distribute the corona discharge throughout the electrode.

Regarding claim 26, Menashi discloses a process for sterilizing containers by generating a plasma (see col. 1, lines 10-20, col. 1, line 69-col. 2, line 8).

9. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Menashi in view of Perruchot et al. as applied to claim 7 above, and further in view of Dusevoir.

Menashi and Perruchot et al. disclose the claimed invention except for a discharge electrode with a surface that is helical.

Dusevoir discloses a discharge electrode (34') for generating a corona discharge that includes an outer sheath (48') having integral ribs (54') helically formed. The helical ribs increase the corona discharge of the electrode (34') by increasing the effective area of the ribs (see col. 2, lines 58-66; see figure 4). Furthermore, the use of long thin solid wire electrodes tend to break easily due to concentration of electrical discharge at certain points thereon and due to material fatigue (see col. 1, lines 25-38).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Menashi and provide a discharge electrode having helical ribs as taught by Dusevoir in order to increase the corona discharge of the electrode and also provide an electrode that will not easily break by using the helical ribs to evenly distribute the corona discharge throughout the electrode.

10. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Menashi in view of Nam et al. as applied to claim 1 above, and further in view of Vavilin et al. (WO 97/22369).

The combination of Menashi and Nam et al. disclose the claimed invention except for a discharge electrode that is inserted into the container being sterilized.

Vavilin et al. discloses a method of sterilizing containers by generating plasma. Two electrodes (5 and 6) are arranged coaxially and are fixed to an insulating plate (17) and connected to a high voltage power supply (3). The electrode (5) is placed centrally within the container to be treated (flask (8)) and the other electrode (6) is located outside of the container. A gas source (4) is also in communication with the inside of the flask (8) for providing the flask (8) with a plasma actuating medium (e.g. argon gas) (see figure 5; page 13, lines 7-17). In use, the power source (3) excites an electric discharge between the electrodes (5) and (6) at atmospheric pressure. The argon gas is fed from source (4) to the region inside the flask (8) where the discharge occurs thus forming plasma in the flask (8) (see page 3, lines 1-20; see page 4, lines 11-19; see page 9, lines 8-10).

Therefore, it would have been an obvious matter of design choice to modify the method of Menashi and place the discharge electrode inside the container and the ground electrode outside of the container since Vavilin et al. discloses that the discharge electrode can be located either inside or outside of the container and still generate a plasma sufficient to sterilize the surfaces of the container.

11. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Menashi in view of Perruchot et al. as applied to claim 7 above, and further in view of Vavilin et al.

The combination of Menashi and Perruchot et al. disclose the claimed invention except for a discharge electrode that is inserted into the container being sterilized.

Vavilin et al. discloses a method of sterilizing containers by generating plasma. Two electrodes (5 and 6) are arranged coaxially and are fixed to an insulating plate (17) and connected to a high voltage power supply (3). The electrode (5) is placed centrally within the container to be treated (flask (8)) and the other electrode (6) is located outside of the container. A gas source (4) is also in communication with the inside of the flask (8) for providing the flask (8) with a plasma actuating medium (e.g. argon gas) (see figure 5; page 13, lines 7-17). In use, the power source (3) excites an electric discharge between the electrodes (5) and (6) at atmospheric pressure. The argon gas is fed from source (4) to the region inside the flask (8) where the discharge occurs thus forming plasma in the flask (8) (see page 3, lines 1-20; see page 4, lines 11-19; see page 9, lines 8-10).

Therefore, it would have been an obvious matter of design choice to modify the method of Menashi and place the discharge electrode inside the container and the ground electrode outside of the container since Vavilin et al. discloses that the discharge electrode can be located either inside or outside of the container and still generate a plasma sufficient to sterilize the surfaces of the container.

12. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Menashi in view of Nam et al. and Dusevoir as applied to claim 2 above, and further in view of Vavilin et al.

The combination of Menashi, Nam et al., and Dusevoir disclose the claimed invention except for a discharge electrode that is inserted into the container being sterilized.

Vavilin et al. discloses a method of sterilizing containers by generating plasma. Two electrodes (5 and 6) are arranged coaxially and are fixed to an insulating plate (17) and connected to a high voltage power supply (3). The electrode (5) is placed centrally within the container to be treated (flask (8)) and the other electrode (6) is located outside of the container. A gas source (4) is also in communication with the inside of the flask (8) for providing the flask (8) with a plasma actuating medium (e.g. argon gas) (see figure 5; page 13, lines 7-17). In use, the power source (3) excites an electric discharge between the electrodes (5) and (6) at atmospheric pressure. The argon gas is fed from source (4) to the region inside the flask (8) where the discharge occurs thus forming plasma in the flask (8) (see page 3, lines 1-20; see page 4, lines 11-19; see page 9, lines 8-10).

Therefore, it would have been an obvious matter of design choice to modify the method of Menashi and place the discharge electrode inside the container and the ground electrode outside of the container since Vavilin et al. discloses that the discharge electrode can be located either inside or outside of the container and still generate a plasma sufficient to sterilize the surfaces of the container.

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13. Claims 28 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Menashi in view of Nam et al. as applied to claim 3 above, and further in view of Vavilin et al.

Regarding claim 28, the combination of Menashi and Nam et al. disclose the claimed invention except for a discharge electrode that is inserted into the container being sterilized.

Vavilin et al. discloses a method of sterilizing containers by generating plasma. Two electrodes (5 and 6) are arranged coaxially and are fixed to an insulating plate (17) and connected to a high voltage power supply (3). The electrode (5) is placed centrally within the container to be treated (flask (8)) and the other electrode (6) is located outside of the container. A gas source (4) is also in communication with the inside of the flask (8) for providing the flask (8) with a plasma actuating medium (e.g. argon gas) (see figure 5; page 13, lines 7-17). In use, the power source (3) excites an electric discharge between the electrodes (5) and (6) at atmospheric pressure. The argon gas is fed from source (4) to the region inside the flask (8) where the discharge occurs thus forming plasma in the flask (8) (see page 3, lines 1-20; see page 4, lines 11-19; see page 9, lines 8-10).

Therefore, it would have been an obvious matter of design choice to modify the method of Menashi and place the discharge electrode inside the container and the ground electrode outside of the container since Vavilin et al. discloses that the discharge electrode can be located either inside or outside of the container and still generate a plasma sufficient to sterilize the surfaces of the container.

Regarding claim 32, Menashi discloses that the gas is selected from the group comprising argon, helium, nitrogen, xenon, and the like (see col. 4, lines 45-52).

Menashi further discloses that the plasma forming gas (e.g. argon) flows down through neck (32) of the gas inlet conduit (31) and sweeps the plasma formed at the corona discharge up through the bottle and out of the opening (see col. 3, lines 25-29, 58-68).

Thus, the gas is introduced during discharge.

14. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Menashi in view of Perruchot et al. as applied to claim 29 above, and further in view of Dusevoir and Vavilin et al.

The combination of Menashi and Perruchot et al. disclose the claimed invention except for a discharge electrode which has unevenness in the form of continuous projections that are helical in shape. Menashi and Perruchot et al. also fail to teach a discharge electrode that is inserted into the container being sterilized.

Dusevoir discloses a discharge electrode (34') for generating a corona discharge that includes an outer sheath (48') having integral ribs (54') helically formed. The helical ribs increase the corona discharge of the electrode (34') by increasing the effective area of the ribs (see col. 2, lines 58-66; see figure 4). Furthermore, the use of long thin solid wire electrodes tend to break easily due to concentration of electrical discharge at certain points thereon and due to material fatigue (see col. 1, lines 25-38).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Menashi and provide a

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discharge electrode having helical ribs as taught by Dusevoir in order to increase the corona discharge of the electrode and also provide an electrode that will not easily break by using the helical ribs to evenly distribute the corona discharge throughout the electrode.

Vavilin et al. discloses a method of sterilizing containers by generating plasma. Two electrodes (5 and 6) are arranged coaxially and are fixed to an insulating plate (17) and connected to a high voltage power supply (3). The electrode (5) is placed centrally within the container to be treated (flask (8)) and the other electrode (6) is located outside of the container. A gas source (4) is also in communication with the inside of the flask (8) for providing the flask (8) with a plasma actuating medium (e.g. argon gas) (see figure 5; page 13, lines 7-17). In use, the power source (3) excites an electric discharge between the electrodes (5) and (6) at atmospheric pressure. The argon gas is fed from source (4) to the region inside the flask (8) where the discharge occurs thus forming plasma in the flask (8) (see page 3, lines 1-20; see page 4, lines 11-19; see page 9, lines 8-10).

Therefore, it would have been an obvious matter of design choice to modify the method of Menashi and place the discharge electrode inside the container and the ground electrode outside of the container since Vavilin et al. discloses that the discharge electrode can be located either inside or outside of the container and still generate a plasma sufficient to sterilize the surfaces of the container.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Conley whose telephone number is 571-272-8414. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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January 16, 2007



GLADYS JP CORCORAN
SUPERVISORY PATENT EXAMINER